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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,115	06/24/2003	Ni Ding	10177-191-999	4829

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
BARRETT, THOMAS C	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/603,115	DING ET AL.	
	Examiner	Art Unit	
	Thomas C. Barrett	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 21, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed September 21, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies, i.e., "a coating or coating portion ***free*** of an elutable drug" (emphasis added), are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Contrary to the Applicant's arguments, and as cited in the prior office action, Berg discloses a plurality of layers, therefore at least an undercoat and topcoat. In column 2, lines 44-67, Berg discloses:

> "The release rate can be further controlled by varying the ratio of drug to polymer in the multiple layers.

Contrary to the Applicant's arguments, Berg does suggest a ***topcoat*** that is ***substantially*** free of an elutable material. The Applicant fails to define or quantify the term "substantially free", which can be read very broadly. In addition, in column 5, lines 12-18, Berg discloses:

> "More polymer may be needed if it has relatively poor efficacy in retaining the therapeutic substance on the stent and more polymer may be needed in order to provide an elution matrix that limits the elution of a very soluble therapeutic substance. A wide ratio of therapeutic substance to polymer could therefore be appropriate and could range from about 10:1 to about 1:100."

Therefore the therapeutic substance to polymer ratio of 1:100 could easily be considered ***substantially*** free of an elutable material.

Please note that even if the Applicant were to argue or amend the claims such that the topcoat was ***substantially*** free of an elutable material as ***compared*** to the other coats, that in column 2, lines 44-67 Berg et al. discloses:

"For example, a higher drug-to-polymer ratio in the outer layers than in the inner layers would result in a higher early dose which would decrease over time."

The above language anticipates the converse, i.e. a higher drug-to-polymer ratio in the ***inner*** layers than in the ***outer*** layers would result in a higher later dose, which would increase over time.

Mitchell et al. was used as a teaching reference for the use of an antibiotic on a stent only, as cited in the prior office action, not for "a coating on a stent".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 51-53, 60-61, 64-65, 69-70, 76-77, 79-83, 90-91, 94-95, 99-100, 106-107 and 109-110 are rejected under 35 U.S.C. 102(a) as being anticipated by Berg et al. (5,464,650). Berg et al. discloses a vascular stent having at least a portion which is implantable into the body of a patient, wherein at least a part of the stent portion is stainless steel (col. 3, lines 37-41) covered with a coating for release of a biologically

active material, wherein said coating adheringly conforms to the stent structure and comprises an undercoat comprising an ethylene vinyl acetate copolymer material incorporating an amount of biologically active material therein for timed release therefrom which acts to inhibit smooth muscle cells in said patient (col. 4, line 35- col. 5, line 39), and wherein said coating further comprises a topcoat which at least partially covers the undercoat, said topcoat comprising a biostable, non-thrombogenic polymeric material which provides long term non-thrombogenicity to the stent portion during and after release of the biologically active material, and wherein said topcoat is substantially free of an elutable material, i.e. ethylene vinyl acetate copolymer. Therapeutic substances, i.e. hirudin, are well known to one of ordinary skill in the art to inherently inhibit smooth muscle cell proliferation (i.e. Vlasuk et al. 5,492,895, col. 5, lines 36-59). Berg et al. discloses that the coating can comprise several layers, therefore having an undercoat and a topcoat.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54-59, 62-63, 66-68, 71-75, 78, 84-89, 92-93, 96-98, 101-105 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (5,464,650) in view of Mitchell et al. (5,288,711). Berg et al. discloses a coated vascular stent as

above however Berg et al. fails to disclose the coating comprising an antibiotic. Mitchell et al. teaches a stent comprising an antibiotic (Rapamycin) to inhibit proliferation of vascular smooth muscle cells (col. 3, lines 7-31). It would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic, as taught by Mitchell et al., to a coated vascular stent as per Berg et al., in order to inhibit proliferation of vascular smooth muscle cells.

Conclusion

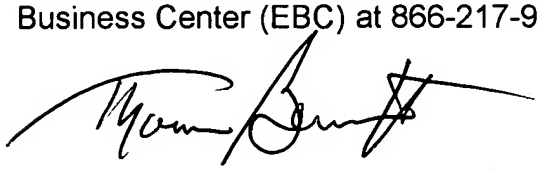
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Thomas Barrett